



**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

**In re Application of:**

Claudio Soto-Jara

**Serial No.:** 10/726,366

**Filed:** December 3, 2003

**For:** USE OF  $\beta$  SHEET BREAKER  
PEPTIDE ANALOGS THAT INHIBIT  $\beta$   
PLEATED SHEET FORMATION IN  
AMYLOID  $\beta$ -PEPTIDE (as amended)

**Confirmation No.:** 8149

**Examiner:** B. Bunner

**Group Art Unit:** 1647

**Attorney Docket No.:** 3154-6317.2US

**NOTICE OF EXPRESS MAILING**

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**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In compliance with the duty to disclose information material to patentability pursuant to 37 C.F.R. § 1.56, it is respectfully requested that this Supplemental Information Disclosure Statement be entered and the documents listed on attached Form PTO/SB/08 be considered by the Examiner and made of record. Copies of U.S. patents are not being submitted pursuant to M.P.E.P. 609 III A(2). Copies of foreign patent documents and non-patent literature are enclosed pursuant to 37 C.F.R. § 1.98(a)(2).

**Serial No.: 10/726,366**

**U.S. Patent Documents**

| <u><b>U.S. Patent No.</b></u> | <u><b>Publication Date</b></u> | <u><b>Patentee</b></u> |
|-------------------------------|--------------------------------|------------------------|
| 5,137,873                     | 08-11-1992                     | Yankner                |
| 6,689,753                     | 02-10-2004                     | Soto-Jara              |

**Foreign Patent Documents**

| <u><b>Document No.</b></u> | <u><b>Publication Date</b></u> | <u><b>Patentee</b></u>                       |
|----------------------------|--------------------------------|--|
| WO 96/28471                | 09-19-1996                     | Pharmaceutical Peptides<br>Incorporated      |
| WO 02/04954 A2             | 01-17-2002                     | Applied Research Systems<br>ARS Holding N.V. |
| WO 03/050139 A2            | 06-19-2003                     | Applied Research Systems<br>ARS Holding N.V. |
| WO 2004/005336 A2          | 01-15-2004                     | Applied Research Systems<br>ARS Holding N.V. |
| WO 2004/050689 A2          | 06-17-2004                     | Applied Research Systems<br>ARS Holding N.V. |
| WO 2004/083243 A1          | 09-30-2004                     | Applied Research Systems<br>ARS Holding N.V. |
| WO 2004/096845 A2          | 11-11-2004                     | Applied Research Systems<br>ARS Holding N.V. |
| WO 2004/111652 A1          | 12-23-2004                     | Applied Research Systems<br>ARS Holding N.V. |

**Other Documents**

BURGESS et al., Possible Dissociation of the Heparin-binding and Mitogenic Activities of Heparin-binding (Acidic Fibroblast) Growth Factor-1 from Its Receptor-binding Activities by Site-directed Mutagenesis of a Single Lysine Residue, The Journal of Cell Biology, 1990, pp. 2129-38, Vol. 111.

DOBELL et al., A Biotechnological Method Provides Access to Aggregation Competent Monomeric Alzheimer's 1-42 Residue Amyloid Peptide, *Biotechnology*, September 13, 1995, pp. 988-93, Vol. 13.

FRASER et al., Conformation and Fibrillogenesis of Alzheimer A $\beta$  Peptides with Selected Substitution of Charged Residues, *J. Mol. Biol.* 1994, pp. 64-73, Vol. 244.

GHISO et al., Unifying Features of Systemic and Cerebral Amyloidosis, *Molecular Neurobiology*, 1994, pp. 49-64, Vol. 8, No. 1.

HILBICH et al., Substitutions of Hydrophobic Amino-Acids Reduce the Amyloidogenicity of Alzheimers-Disease Beta-A4 Peptides, *Journal of Molecular Biology*, November 20, 1992, Vol. 228, No. 2.

KELLY et al., Alternative conformations of amyloidogenic proteins govern their behavior, 1996, pp. 11-17, Vol. 6.

LAZAR et al., Transforming Growth Factor  $\alpha$ : Mutation of Aspartic Acid 47 and Leucine 48 Results in Different Biological Activities, *Molecular and Cellular Biology*, Mar. 1988, pp. 1247-52, Vol. 8, No. 3.

MERLINI et al., Interaction of the anthracycline 4'-iodo-4'-deoxydoxorubicin with amyloid fibrils: Inhibition of amyloidogenesis, *Proc. Natl. Acad. Sci.*, March 1995, pp. 2959-2963, Vol. 92, USA.

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RUDINGER, Characteristics of the amino acids as components of a peptide hormone sequence, Jun. 1976, pp 1-7, In *Peptide Hormones*, Parsons (ed.), University Park Press, Baltimore.

SOTO et al., Abstract, Structural Determinants of the Alzheimers Amyloid Beta-Peptide, *Journal of Neurochemistry*, 1994, pp. 1191-98, Vol. 63.

SOTO et al., Abstract, Two Conformational States of Amyloid Beta-Peptide - Implications for the Pathogenesis of Alzheimers-Disease, February 17, 1995, pp. 115-18, Vol. 186.

SOTO et al., Fibrillogenesis of synthetic amyloid- $\beta$  peptides is dependent on their initial secondary structure, *Neuroscience Letters* 200, 1995, pp. 105-08.

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SOTO et al., The  $\alpha$ -Helical to  $\beta$ -Strand Transition in the Amino-terminal Fragment of the Amyloid  $\beta$ -Peptide Modulates Amyloid Formation, *The Journal of Biological Chemistry*, 1995, pp. 3063-3067, Vol. 270, No. 7.

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This Supplemental Information Disclosure Statement is filed after the mailing date of the first Office Action on the merits.

The fee pursuant to 37 C.F.R. § 1.17(p) is enclosed.

Serial No.: 10/726,366

Respectfully submitted,

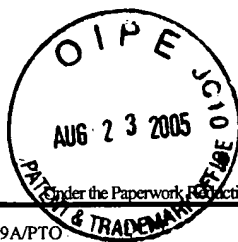
A handwritten signature in black ink, appearing to read 'G. Scott Dorland', written over a horizontal line.

G. Scott Dorland, Ph.D.  
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Date: June 29, 2005  
GSD/bv

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

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Sheet

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of

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**Complete if Known**

|                        |                   |
|------------------------|-------------------|
| Application Number     | 10/726,366        |
| Filing Date            | December 3, 2003  |
| First Named Inventor   | Claudio Soto-Jara |
| Group Art Unit         | 1647              |
| Examiner Name          | B. Bunner         |
| Attorney Docket Number | 3154-6317.2US     |

**U.S. PATENT DOCUMENTS**

| Examiner<br>Initials * | Cite<br>No. <sup>1</sup> | Document Number                            | Publication Date<br>MM-DD-YYYY | Name of Patentee or Applicant of<br>Cited Document | Pages, Columns, Lines, Where Relevant<br>Passages or Relevant<br>Figures Appear |
|------------------------|--------------------------|--|--------------------------------|--|---|
|                        |                          | Number - Kind Code <sup>2</sup> (if known) |                                |  |   |
|                        |                          | US- 5,137,873                              | 08-11-1992                     | Yankner  |   |
|                        |                          | US- 6,689,753                              | 02-10-2004                     | Soto-Jara  |   |
|                        |                          | US-  |                                |  |   |
|                        |                          | US-  |                                |  |   |
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|                        |                          | US-  |                                |  |   |
|                        |                          | US-  |                                |  |   |
|                        |                          | US-  |                                |  |   |

**FOREIGN PATENT DOCUMENTS**

| Examiner<br>Initials * | Cite<br>No. <sup>1</sup> | Foreign Patent Document   | Publication Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited<br>Document | Pages, Columns, Lines,<br>Where Relevant Passages or<br>Relevant Figures Appear | T <sup>6</sup> |
|------------------------|--------------------------|---|--------------------------------|---|---|----------------|
|                        |                          | Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known) |                                |   |   |                |
|                        |                          | WO 96/28471   | 09-19-1996                     | Pharmaceutical<br>Peptides Incorporated               |   |                |
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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

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Sheet 2 of 3

**Complete if Known**

|                        |                   |
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| Group Art Unit         | 1647              |
| Examiner Name          | B. Bunner         |
| Attorney Docket Number | 3154-6317.2US     |

**OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS**

| Examiner<br>Initials * | Cite<br>No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.                                      | T <sup>2</sup> |
|------------------------|--------------------------|--|----------------|
|                        |                          | BURGESS et al., Possible Dissociation of the Heparin-binding and Mitogenic Activities of Heparin-binding (Acidic Fibroblast) Growth Factor-1 from Its Receptor-binding Activities by Site-directed Mutagenesis of a Single Lysine Residue, The Journal of Cell Biology, 1990, pp. 2129-38, Vol. 111. |                |
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|                        |                          | PIKE et al., Structure-Activity Analyses of $\beta$ -Amyloid Peptides: Contributions of the $\beta$ 25-35 Region to Aggregation and Neurotoxicity, Journal of Neurochemistry, January 1995, pp. 253-65, Vol. 64, No. 1.  |                |
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